

REMARKS

The issues outstanding in the office action mailed January 29, 2007, are the objections to the claims and the rejections under 35 U.S.C. §112 and §102. Reconsideration of these issues, in view of the following discussion, is respectfully requested.

Objections to Claims

Claims 1 and 10 have been objected to as a result of a misspelling, and a use of the hyphen. The examiner is thanked for noting these issues. Appropriate correction has been made in the present amendment, and withdrawal of the objection is respectfully requested.

Rejections under 35 U.S.C. §112

Claims 1-2 and 4-9 have been rejected under 35 U.S.C. §112, first paragraph. It is argued at page 3 of the Office Action that the specification does not provide the written description for a method of "directly and completely" immersing the tissue in a treating solution. At the outset, it is noted that cancellation of Claim 1, an amendment of the claims to depend upon Claim 10, which is not subject to this rejection, obviates the issue. However, for clarity, applicants wish to emphasize that such complete and direct immersion is clearly supported in the present specification, e.g., in the examples. In any event, this issue is moot.

Claims 1-2 and 4-9 have also been rejected under 35 U.S.C. §112, second paragraph, and it is argued that the phrase "a period of time to substantially decellularize said tissue is unclear. Again, this issue is moot in view of the cancellation of Claim 1. However, it is noted that, even if the assertions at page 4 of the Office Action (that different tissues would require different amounts of time) are accurate, it is submitted that determination of an appropriate time is mere routine experimentation and conventional in the art. Where one of ordinary skill in this art would clearly understand the meaning of the term, and moreover, be able to practice the invention, there is no indefiniteness. In any event, it is again submitted that the issue is moot. Withdrawal of all rejections under 35 U.S.C. §112 is respectfully requested.

Rejections under 35 U.S.C. §102

Claims 10 has been rejected under 35 U.S.C. §102(b) over Anderson et al. (U.S. '216). Reconsideration of this rejection is respectfully requested.

It is believed that there may be a fundamental misunderstanding of the teachings of Anderson. Particularly, at page 5 of the Office Action, it is argued that the reference recited a "method of decellularizing native tissue of mammalian origin comprising immersing said tissue in a treating solution, and irradiating the tissue with microwaves..." In fact, Anderson discloses *alternative* methods of decellularization, one involving immersing tissue in a heating bath, and a *separate* alternative involving the use of microwaves. Columns 6, lines 1-6 of the reference, cited at page 5 of the Office Action for the disclosure of microwaves, pertain to an embodiment of the invention wherein a probe is inserted into an incision, and heats the tissue of the incision to the desired temperature. Patentees teach that the probe is withdrawn from the incision, allowing the two cut surfaces thereof to weld together. See, for example, column 5, lines 60-65. As representative heating devices, i.e., probes, patentees disclose lasers, and radio frequency or microwave heaters, see column 6, lines 1-2. The disclosure of column 6 thus does not teach the use of microwave heating *in conjunction* with a liquid bath. An additional alternative of the invention, that disclosed at column 8, in the examples, also noted at page 5 of the Office Action, involves an embodiment of the invention (useable, clearly, in a laboratory setting) where tissue samples were cut into disks, which disks were place between sealed microscope cover slides, and immersed in a circular water bath at different temperatures for different times. See column 8, lines 28-33. Patentees teach that this "model" is used to determine weld strength after different cross-linking methods. Such a welding bath, which does not use microwave heating, is clearly a laboratory technique used to assess cross-linking which is discussed previously in the patent at columns 6-8. However, in no way do patentees teach the use of the microwave probe in conjunction with the laboratory technique of heating in the welding bath. Indeed, the use of two separate heating sources would be unnecessary, and the patent does not instruct one of ordinary skill how to do so. Accordingly, it is clear that Claim 10, which recites immersing tissue in a treating solution *and* irradiating the tissue with microwaves is simply not taught by the reference, nor is it suggested inasmuch as the *combination* of two or more heating methods is

simply not taught by patentees. Withdrawal of this rejection is therefore respectfully requested.

Claims 1-2 and 4-9 have been rejected under 35 U.S.C. §102(b) over Anderson. It is submitted that this rejection is moot. Moreover, the steps of the presently claimed method are *not* the same as Anderson, inasmuch as Anderson does not teach the combination of microwave heating and immersion. In any event, it is again maintained that the rejection is moot.

The claims in the application are submitted to be in condition for allowance. However, if the examiner has any questions or comments, she is cordially invited to telephone the undersigned at the number below.

Respectfully submitted,

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